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DK

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/191,997	11/13/98	EDWARDS - J	GENSET016A

020995 HM12/0210
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EXAMINER	
O HARA, E	
ART UNIT	**PAPER NUMBER**
1646	5

DATE MAILED: 02/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/191,997	Dumas Milne Edwards et al.
Examiner	**Group Art Unit**
Eileen B. O'Hara	1646

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____1_____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-18* _____ is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-18* _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Claims 1-18 are pending in the instant application.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 13, 14, 16 and 18, in so far as they are drawn to polynucleotides comprising SEQ ID NOS: 134-180, respectively, and encoding polypeptides, as well as vectors, host cells and a method of producing polypeptides, classified in class 536, subclass 23.5, class 435, subclasses 320.1, 252.3 and 69.1.

II. Claims 9-12 and 15, in so far as they are drawn to polypeptides comprising SEQ ID NOS: 181-227 respectively, classified in class 530, subclass 351, for example.

III. Claim 17, in so far as it is drawn to antibodies to polypeptides comprising SEQ ID NOS: 181-227 respectively, classified in class 530, subclass 388.22, for example.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Invention I are related to the proteins of Invention II by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in claim 13. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification

from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The proteins of Invention II are related to the antibodies of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although each protein and it's antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand or receptor of the protein, or in assays for the identification of agonists or antagonists of the protein.

The nucleic acids of Invention I are distinct from the antibodies of Inventions III because they are physically and functionally distinct chemical entities which share neither structure nor function. Invention I and invention III are related as a process of making and a process of using a common product. The polynucleotides of invention I encode the polypeptide, which is the cognate antigen necessary for production of the antibody of invention III and which is used in the method of identifying a compound binding to the polypeptide, but the nucleotides may also be used as probes in a method of hybridization, which are materially different methods. The processess are patentably distinct because of different starting and ending points, method steps and goals.

Additionally:

If applicant elects Invention I, applicant is required to specify no more than ten specific nucleotide sequences for examination. This requirement is made under O.G. Notice 1192 O.G. 68 (November 19, 1996), as the examination of more than ten sequences in one application would result in an undue search burden on the PTO.

If applicant elects Invention II or III:

This application contains claims directed to the following patentably distinct species of the claimed invention: each protein or antibody which corresponds to an individual sequence disclosed in the specification comprises a patentably distinct species of invention, as each particular protein or antibody has a distinct physical and chemical structure, properties and function. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of either protein or antibody for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D

Eileen B. O'Hara 2/10/00

Patent Examiner

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER